Oncocyte and Bio-Rad Partner on Global Launch of Transplant Assay

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- Bio-Rad expects to make equity investment in support of deal
- Agreement provides for global exclusivity in transplant monitoring commercialization
- Bio-Rad granted subsequent investment option upon FDA clearance

IRVINE, Calif., April 11, 2024 (GLOBE NEWSWIRE) -- Oncocyte Corporation (Nasdaq: OCX), a precision diagnostics company, today announced a partnership agreement with Bio-Rad Laboratories (NYSE: BIO), a global leader in life science research and clinical diagnostics products, for the commercialization of its research use only GraftAssure™ assay, powered by Droplet Digital™ PCR (ddPCR™)*. The new product is expected to launch in Q2 2024 to a select group of academic transplant centers in the US and EU and more broadly in the second half of the year.

As part of the agreement, Bio-Rad and Oncocyte will co-market the assay inside the US and Germany, with Oncocyte acting as commercial lead. Outside these countries Bio-Rad has been granted exclusive global distribution and commercial rights.

“As we move towards launch, having the support of the Bio-Rad team in the US and Germany gives us the scale we need to meet the market opportunity,” said Josh Riggs, Oncocyte’s CEO. “The QX600 ddPCR platform, along with their expertise in serving the life science market, makes Bio-Rad a natural partner for our transplant technology.”

Going forward, both companies have committed to joint efforts in developing a regulated product designed to facilitate widespread distribution and clinical adoption in the United States and beyond.

Additionally, Bio-Rad has been granted an option for IVD commercial rights at FDA clearance, subject to meeting specific objectives. Exercising the option would come with a second equity investment into Oncocyte. Further details of the agreement can be found in Oncocyte’s filing with the Securities and Exchange Commission.

dd-cfDNA is a proven, non-invasive biomarker with growing demand offering an estimated three million testing opportunities globally and driving a market exceeding $1 billion. Globally, over 157,000 transplants are performed with a 9.1% annual growth rate. GraftAssure™ uses a differentiated technology, Droplet Digital PCR to quantify dd-cfDNA to detect signs of graft damage.

*Droplet Digital, ddPCR and QX600 are trademarks of Bio-Rad Laboratories, Inc.

AboutOncocyte

Oncocyte is a precision diagnostics company. The Company's tests are designed to help provide clarity and confidence to physicians and their patients. VitaGraft™ is a clinical blood- based solid organ transplantation monitoring test, which recently received CMS reimbursement for kidney transplantation. GraftAssure™ is a decentralized research use only blood-based solid organ transplantation monitoring test, DetermaIO™ is a gene expression test that assesses the tumor microenvironment to predict response to immunotherapies, and the pipeline test DetermaCNI™ is blood-based monitoring tool for assessing therapeutic efficacy.

VitaGraft™, GraftAssure™, DetermaIO™, and DetermaCNI™ are trademarks of Oncocyte Corporation.

Forward-LookingStatements

Any statements that are not historical fact (including, but not limited to statements that contain words such as "will," "believes," "plans," "anticipates," "expects," "estimates," "may," and similar expressions) are forward-looking statements. These statements include those pertaining to, among other things, the expected launch of the new GraftAssure product in 2Q 2024 to a select group of academic transplant centers in the US and EU and more broadly in the second half of the year, the transactions contemplated by the Collaboration Agreement, the expectation of meeting the market opportunity, the anticipated development of a regulated product and system designed to facilitate widespread distribution and clinical adoption of the core technology in the United States and beyond, the expectation for FDA clearance, the possibility that Bio-Rad will exercise its option for IVD commercial rights and with a second equity investment, , and other statements about the future expectations, beliefs, goals, plans, or prospects expressed by management. Forward-looking statements involve risks and uncertainties, including, without limitation, risks inherent in the development and/or commercialization of diagnostic tests or products, uncertainty in the results of clinical trials or regulatory approvals, the capacity of Oncocyte's third-party supplied blood sample analytic system to provide consistent and precise analytic results on a commercial scale, potential interruptions to supply chains, the need and ability to obtain future capital, maintenance of intellectual property rights in all applicable jurisdictions, obligations to third parties with respect to licensed or acquired technology and products, the need to obtain third party reimbursement for patients' use of any diagnostic tests Oncocyte or its subsidiaries commercialize in applicable jurisdictions, and risks inherent in strategic transactions such as the potential failure to realize anticipated benefits, legal, regulatory or political changes in the applicable jurisdictions, accounting and quality controls, potential greater than estimated allocations of resources to develop and commercialize technologies, or potential failure to maintain any laboratory accreditation or certification. Actual results may differ materially from the results anticipated in these forward-looking statements and accordingly such statements should be evaluated together with the many uncertainties that affect the business of Oncocyte, particularly those mentioned in the "Risk Factors" and other cautionary statements found in Oncocyte's Securities and Exchange Commission (SEC) filings, which are available from the SEC's website. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date on which they were made. Oncocyte undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.

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